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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,674	05/23/2001	C. Frederick Battrell	5SMV41.1	1283

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EXAMINER	
SIEFKE, SAMUEL P	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,674	BATTRELL ET AL.	
	Examiner	Art Unit	
	Samuel P. Siefke	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/10/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **18** and **21** are rejected under 35 U.S.C. 102(e) as being anticipated by Forster et al. (USPN 6,134,950).

Forster discloses a method for determining concentration of a laminar sample stream that comprises: providing a microfluidic channel (fig. 1); introducing a first fluid containing a diffusible constituent into the first inlet (fig 1, ref.30); introducing a second fluid into a second inlet (fig. 1, ref. 20); flowing the first and second fluids through channel (100) in parallel laminar flow (abstract) so that the diffusible constituents diffuse between the first fluid and the second fluid to form a single combined fluid stream which has uniform composition across the width of the microfluidic channel (col. 9, lines 41-59); varying the flow rate of the first fluid and the second fluid such that he ratio of the flow rates of the first and second fluid is not constant and the concentration of the

diffusible constituent in the singe combined fluid stream varies along the length of the microfluidic channel (col. 11, lines 14-25; col. 10, lines 58-64). The diffusible constituent can be soluble (col. 2 ,lines 47-56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **19-20** and **22-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Forster et al. (USPN 6,134,950) in view of Weigl et al. (USPN 6,171,865).

Forster discloses a method for determining concentration of a laminar sample stream as discussed above.

Forster does not teach introducing a third fluid containing a particulate material into a third inlet.

Weigl teaches a method for simultaneous analyte determination that comprises introducing a third fluid into a third fluid inlet (fig. 3, ref. 25A), the third fluid (75A) and the first fluid (80) surround the second fluid (70A) in the channel, wherein the diffusible constituents diffuse into the second fluid (fig. 3, ref. 140A and 145A; col. 25, lines 24-28); thus diluting the second fluid such that the concentration of the second fluid is gradually decreased with the distance from a section of the channel where first and second fluids contact each other (fig. 3, noting all references of the 1st, 2nd, and 3rd inlets moving toward the exit port; col. 24, line 64-col. 25, line 46). The first and third fluids are introduced through a first and third inlet from a common inlet (this common inlet will be described as the channel in which all the inlets come together in Fig. 3, ref. 100). The microfluidic device is located on a chip (col. 9, lines 62-67). Measurements can be taken on any part of the microfluidic device (col. 9, lines 1-22). The diffusible constituent consists of a soluble compound, biological material (cells, proteins); (col. 10, line 48-col. 11, line 11). The fluid from the second inlet comprises undissolved particles (microbeads) (col. 14, lines 58-col. 15, line 12). Other important parts of the specification of the reference that describe the prior art or further the invention (col. 3, lines 1-16 and 55-67; col. 5; col. 6, lines 4-14; fig. 1-7; col. 7-18; col. 22, line 13-col. 26, line 39; claims 1-22). It would have been obvious to one having an ordinary skill in the art to modify Forster to include introducing a third fluid containing a particulate material into a third inlet in order to provide additional indicators so that multiple detections can

be carried out on one sample. With respect to the microbeads or biological cells being in the third fluid, it would have been obvious to one of ordinary skill in the art to modify Forster to allow the microbeads or cells to be in either introduced into inlet 2 or 3 because both streams would eventually become a uniform stream. Therefore no matter where the microbeads or cells are introduced they will be distributed to the entire microfluidic channel (col. 11, lines 14-25; col. 10, lines 58-64).

Response to Arguments

Applicant's arguments filed 11/10/05 have been fully considered but they are not persuasive. Applicant argues, "With respect to the first element noted above, namely, the formation of a single combined fluid stream having a uniform composition across the width of the microfluidic channel, it appears the Examiner is interpreting this limitation as merely requiring that the diffusible constituent is uniformly distributed across the width of the microfluidic channel. Applicants disagree. The language of pending independent claim 18 is not limited in the manner the Examiner asserts. To the contrary, claim 18 broadly recites "a single combined fluid stream which has a uniform composition across the width of the microfluidic channel." In other words, claim 18 requires that the entire composition (not just the concentration of the diffusible constituent) of the fluid stream is uniform. Claim 18 only requires that the first fluid contain a diffusible constituent, then flowing the first and second fluids through the microfluidic channel in parallel laminar flow such that the diffusible constituent (from the first fluid) diffuses between the first

fluid and the second fluid to form a single combined fluid stream (2 streams are now 1) which has a uniform composition across (occurs at the end of the channel) the width of the microfluidic channel. Uniform composition occurs when the channel 100 is long enough for the two sample streams to combine. When the diffusible constituent from the first fluid diffuses into the second fluid it creates an equilibrium of diffusible constituents across the entire width of the flow channel. This occurs because the diffusible constituent can diffuse into the second fluid then back into the first fluid as an equal distribution of diffusible constituents occurs while flowing downstream until equilibrium or a uniform composition of diffusible constituents is created across the width of the microfluidic channel. Foster discloses that particles of an indicator substance, e.g. dye particles, may also diffuse into the sample stream 80 to form a diffused indicator area 110 (col. 9, line 67- col. 10 ,line 2). This further shows that there is cross diffusion between sample and indicator stream which ultimately ends further down the channel in a uniform composition across the entire width of the stream. The instant claims are directed to a parallel laminar flow channel. This is exactly the apparatus of Foster discloses. Why should the instant parallel laminar flow channel mix any different that channel of Foster? Foster discloses each and every limitation above.

Applicant argues, "Although Forster discloses that the first and second fluid streams may be flowing at different rates, Forster does not disclose that the first and second fluid streams may be flowing at variable rates... the method of pending independent claim 18 requires that (i) at least one of the flow rates is varied (i.e., not constant) and (ii) the ratio of the flow rates of the first and second fluids is not constant."

On top of the other arguments presented throughout prosecution, the Examiner points to Example 2 of Foster where equivalence of alteration of flow rates and particle diffusion patterns is discussed. The point of this example is to show that varied flow rates of the inputs of the sample stream and the indicator stream will change how rapidly the diffusion particles diffuse into the indicator stream see figures 3 and 4.

Conclusion

This is a first Office Action Final because the RCE did not present any amendment to the claims or new arguments. The same rejection is being applied to the claims as in the Final Office Action dated 5/10/05.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

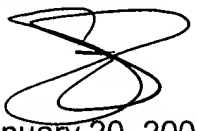
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



January 20, 2006

Jill Warden
Supervisory Patent Examiner
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